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Food and Drug Administration
Washington DC 20204

JUN 25 2001

WARNING LETTER
ONPLDS 19-01

BY CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Dave Day
President
Nu-Day Snacks, Inc.
11650 NW 56th Dr., Apt. 101
Coral Springs, Florida 33076

Dear Mr. Day:

The Food and Drug Administration (FDA) has reviewed the label for your Perfect Protein Cookie. Our review reveals that this label causes the above product to be in violation of the Federal Food, Drug, and Cosmetic Act (the Act) and Title 21, Code of Federal Regulations (21 CFR).

This product is misbranded because the label bears the nutrient content claim "low carbs" that is not authorized by regulation or the Act (Section 403(r)(1)(A)).

The product is also misbranded because the claim "low fat" is not followed by the criteria for the claim (e.g., Low fat – 3 grams or less of fat per 40 grams of product) (21 CFR 101.13(p)). The product appears to meet the criteria for "low fat" on the basis of the reference amount customarily consumed (RACC). However, the serving size declared on the product differs from the RACC, and the amount of fat in the labeled serving does not meet the minimum amount in the definition for "low fat" (21 CFR 101.62(b)(2)).

The product is further misbranded because the label bears the statement "We do not include the polyols in the carbohydrate count..." Sugar alcohols are carbohydrates and must be included in the value declared for "Total Carbohydrate" in nutrition labeling (Sections 403(a), 403(q) and 21 CFR 101.9(c)(6)).

The above violations are not meant to be an all inclusive list of deficiencies on your label. It is your responsibility to ensure that all of your products are labeled in compliance with the laws and regulations enforced by FDA. You should take prompt action to correct these deviations and prevent their future recurrence. Failure to make prompt corrections could result in regulatory action without further notice. Possible actions include seizure and/or injunction.

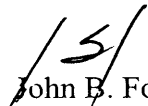
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As some additional information, the label fails to provide a complete address in that there is no city or zip code listed. We further advise that if the food is not manufactured by the firm whose name appears on the label the firm's name must be qualified to reveal the connection to the food (see 21 CFR 101.5).

Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken or plan to take to correct the noted violations. Copies of revised labels for the product should be submitted. If corrective actions cannot be completed within 15 working days, state the reason for delay and the time within which corrections will be completed.

You should direct your written reply to me at the Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Nutritional Products, Labeling and Dietary Supplements (HFS-810), 200 C Street, S.W., Washington, D.C. 20204.

Sincerely yours,


John B. Foret
Director
Division of Compliance
and Enforcement
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition